

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: M. REDMON et al.

Application No.: Unassigned (continuation-in-part of application nos. 09/719,843, filed November 21, 2000 and 09/721,711, filed November 27, 2000)

Group Art Unit: 1615

Examiner: L. Channavajjala

Filed: February 15, 2002

Attorney Docket No.: 4821-464

For: PHARMACEUTICAL COMPOSITIONS
COMPRISING NORASTEMIZOLE

PRELIMINARY AMENDMENT

Box PATENT APPLICATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-captioned application, which is a continuation-in-part of pending Application No. 09/719,843, filed November 21, 2000, which is a 371 of PCT/US98/05701, which is a continuation-in-part of pending Application No. 08/851,786, filed May 6, 1997, which is a continuation-in-part of pending Application No. 08/824,477, filed March 26, 1997; and is a continuation-in-part of pending Application No. 09/721,711, filed November 27, 2000, which is a continuation-in-part of pending Application No. 08/851,786, filed May 6, 1997, which is a continuation-in-part of pending Application No. 08/824,477, filed March 26, 1997, please enter the following remarks into the record thereof.

REMARKS

Claims 1-40 are pending for the Examiner's review and consideration. Claims 1-8 recite solid pharmaceutical compositions comprising norastemizole, or a pharmaceutically acceptable salt thereof; a diluent; a binder; a disintegrant; and a lubricant, wherein the disintegrant and lubricant are not the same. Claims 9-15 recite solid pharmaceutical composition comprising norastemizole, or a pharmaceutically acceptable salt thereof; microcrystalline cellulose; pregelatinized starch; croscarmellose sodium; and magnesium

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stearate. Claims 16-21 recite a solid pharmaceutical composition comprising (i) a therapeutically effective amount of coated particles of norastemizole, or a pharmaceutically acceptable salt thereof, wherein said particles are coated with an inert coating and (ii) a pharmaceutically acceptable excipient. Claims 22-24 recite a solid pharmaceutical composition comprising norastemizole, or a pharmaceutically acceptable salt thereof; a diluent; a binder; a disintegrant; and a lubricant; wherein the disintegrant is a super disintegrant. Claims 25-40 recite methods of treating allergic disorders in a mammal comprising administering to the mammal a therapeutically effective amount of the composition of claim 1 (claims 25-28), claim 9 (claims 29-32), claim 16 (claims 33-36), or claim 22 (claims 37-40). Claims 1-6, 9, 11-13, 16-19, 22-27, 29-31, 33-35, and 37-39 are supported by the parent applications (application nos. 09/719,843 and 09/721,711).

The specification was amended to delete the discussion at page 10 of parent application no. 09/719,843 beginning with the word "However" at line 9 to the word "use" at line 14 and to replace the word "Moreover" at page 10, line 14 with the word --However--. Similarly, the specification was amended to delete the discussion at page 5 of parent application no. 09/721,711 beginning with the word "However" at line 13 to the word "use" at line 18 and to replace the word "Moreover" at page 5, line 18 with the word --However--.

The deleted sections of the specifications of the parent applications discuss a prophetic lactose free norastemizole composition disclosed in PCT/US93/08349 ("PCT '349"). Specifically, the specification in the parent applications stated that the formulation disclosed in PCT '349 is "unsuitable for actual pharmaceutical use." Applicants recently discovered that this statement may be incorrect. Although one would expect magnesium stearate BP and Starch 1500 to be incompatible at the weight percentages disclosed in PCT '349 and, thus, be unsuitable for pharmaceutical use, as noted in the parent applications, Applicants have now been able to make the formulation disclosed in PCT '349 and it does actually meet United States Pharmacopeia standards. Therefore the formulation disclosed in PCT '349 may be suitable for pharmaceutical use. Accordingly, the discussion in the specification of each parent application that the formulation disclosed in PCT '349 is "unsuitable for actual pharmaceutical use" has been deleted from the present application. Furthermore, Applicants respectfully rescind any arguments previously made to the United States Patent and Trademark Office that the formulation disclosed in PCT '349 is "unsuitable

for actual pharmaceutical use." Entry of the foregoing remarks prior to examination is respectfully requested. An early allowance is earnestly sought.

No fee is believed to be due for this submission. Should any fees be required, however, please charge the required fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Paul E. Ditz (45,627)

Date: February 15, 2002

for Anthony M. Insogna 35,203

Anthony M. Insogna (Reg. No.)

PENNIE & EDMONDS LLP

1667 K Street, N.W.

Washington, DC 20006

(202) 496-4400

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